K091548

*Braun*Solutions®

AUG 07 2009

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510(k) Summary
(Per 21 CFR 807.92)

Submitter/Owner:
Amco International Manufacturing & Design, Inc.
Attn: Mr. Adam Milewski
Medical Battery Division
10 Conselyea Street,
Brooklyn, NY 11211 USA

Official Correspondent:
Alexander B. Henderson
BraunSolutions
377 Zane Court,
Elizabeth, CO 80107 USA
Tel: 303-646-3715
Email: alex_henderson@msn.com

Date Prepared:
May 18, 2009

Device Name:
Battery Pack, Disposable

Trade/Proprietary Name: AMCO™ Battery Pack
Common/Generic Name: Box, Battery
Classification Name: Box, Battery, Non-Rechargeable
Regulatory Class III, Product Code MKJ

Predicate Devices:
Philips Medical Replacement Battery
ForeRunner BT1 Defibrillator
- Approved under K955628
Philips Medical Replacement Battery
HeartStart FRx On-Site / Home AED
- Approved under K020715, K040904, K050004

Classification:	**Cardiovascular Panel**	**Class**
21 CFR 870.5300	DC-Defibrillator	III
21 CFR 870.5310	Automated External Defibrillator	III

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510(k) Summary

AMCO Replacement Battery Packs
5L318 and AM5070

Legally Marketed Predicate Devices:

The Amco 5L318 is the same as the Philips Medical / Agilent replacement battery BT1 used in the ForeRunner and HeartStart FR AED's.

The Amco AM5070 is the same as the Philips Medical replacement battery M5070A used in the HeartStream / HeartStart FRx On-Site and Home (OTC) AED's.

These HeartStream / Philips Medical / Agilent battery packs were most likely bundled in the original submission(s) as accessories.

Device Description:

Non-rechargeable battery packs are utilized as a primary direct current (d-c) power source or as a standby or backup d-c power source for portable as well as stationary medical equipment. These devices provide a means of supplying electrical power through chemical reaction. The energy provided depends upon the voltage and capacity rating of a particular pack and the amount of current used by the device into which they are installed. The performance and life span of these batteries depends on operating conditions of temperature, current drain, and the discharge method. These parameters are taken into account in designing such batteries. The goal is to develop battery packs that maintain capacity for as high and as long as possible under a specified range of environmental conditions.

Statement of Intended Use:

To power the specific HeartStream / Philips Medical / Agilent AED's for which these replacement battery packs are intended. Only qualified personnel, such as Biomedical Engineers, Medical Clinics, EMT's, etc., should evaluate, test, or install these battery packs.

Substantial Equivalence:

The design components and functionality of the AMCO™ 5L318 and AM5070 battery packs are identical to those of their predicate devices. Cell chemistry and type are identical, Sealed (Vented) Lithium / Manganese Dioxide (Li/MnO2).

Reference: Substantial Equivalence Comparison Charts – Section B, Page 1.

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Conclusions:

Amco International Manufacturing and Design, Inc. has demonstrated through its continued evaluation and testing of the AMCO™ 5L318 and AM5070 replacement battery packs, that these devices are equivalent to the HeartStream / Philips Medical / Agilent battery packs, as outlined in this submission.

The AMCO™ 5L318 and AM5070 replacement battery packs are identical with respect to indications for use, technological characteristics, materials, form. fit, and function to those currently distributed commercially. This notification contains all information required by 21 CFR 807.87. A completed copy of the Premarket Notification 510(k) Reviewer's Checklist is provided in this submission

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-0609
Silver Spring, MD 20993-0002

Amco International Manufacturing & Design, Inc.
c/o Mr. Alexander B. Henderson
Braun Solutions
377 Zane Court
Elizabeth, Colorado 80107

AUG 07 2009

Re: K091548
Trade/Device Name: Model 5L318 battery and Model AM5070 battery
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillator
Regulatory Class: Class III
Dated: May 26, 2009
Received: May 27, 2009

Dear Mr. Henderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K091548

Device Name: AMCO Replacement Battery Packs 5L318 and AM5070

Indications for Use:

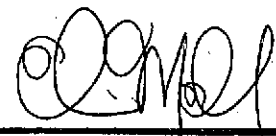
The 5L318 Lithium/Manganese Dioxide (Li/MnO2) AMCO battery is a disposable replacement battery pack for use in the Philips Medical / HeartStream ForeRunner AED; specifically Philips Medical battery part number BT1. This battery has a shelf life of 4 years from the date of manufacture.

The AM5070 Lithium/Manganese Dioxide (Li/MnO2) AMCO battery is a disposable replacement battery pack for use in the Philips Medical / HeartStream FRx and HeartStart Home AED; specifically Philips Medical battery part number AM5070A. This battery has a shelf life of 4 years from the date of manufacture.

Prescription Use ___√___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K091548